

Patient generated data

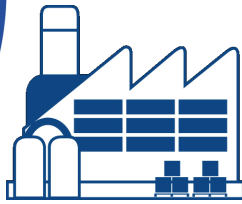
Patients would generate different data all along the medicines' life-cycle

François Houyez

Real-time feedback – COVID-19, France

Renaloo, social network of patients with kidney transplant or dialysis

- 22 June to 12 July 2020: 2,030 respondents / 10,000 members
 - Only 33% had a direct contact with nephrologist during the 2-month lockdown
 - 25% of those on renal transplant waiting list: not informed of the suspension of adult kidney transplantation
- 4 to 23 February 2021: 2,300 respondents
 - 96% were or wished to be vaccinated (versus 64% in general population at that time)
- July 2021: 2,389 respondents
 - 85.4% dialysed and 87.8% transplanted got at least one vaccine dose
- October 2021
 - 2 months after Ronapreve® CU started, despite “[DGS urgent](#)” only 2% of 57,000 patients (CU indication) were treated
- March 2022
 - > 75% of kidney transplant patients inadequately protected by vaccination still not received Evusheld® prophylaxis (CU opened December 2021)



These are our needs.
Which technology can help?
How to measure effect?

Here's a candidate
technology. How to
develop it?

Healthcare
RWD

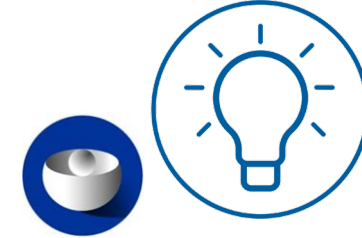


Methods

Surveys, Mixed methods,
PRelevantOs, GAS...

**Patient
Engagement**

Community Advisory
Boards (CABs)
NEEDs project



HTA

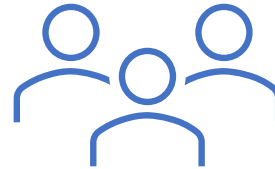
Methods

Own data entry,
Connected devices,
registries

**Patient
Engagement**

Governance in data
sources

Patients
generate data



Methods

Qualitative

**Patient
Engagement**

Scientific Advice

Decision-making



HTA

Methods

Qualitative: expectations, what matters
Best Worst Scaling: ranking, priorities
DCE: to which extent? PPE
Spontaneous reporting susp. ADRs

Patient Engagement

CHMP Early contribution, (Effects Table)
SAG, consultations (B/R, pharmacovigilance...)
HTA and appraisal



Methods

PPE Study

**Patient
Engagement**

CABs



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 September 2025
EMA/CHMP/PRAC/148869/2025

Reflection paper on patient experience data

Table of contents

1. Introduction	3
1.1. Background	3
1.2. Problem statement	3
1.3. Scope	4
2. Discussion	4
2.1. The EU regulatory approach to patient experience data	4
2.1.1. Patient experience data	4
2.1.2. The Agency's view on patient experience data	5
2.2. Use and value of patient experience data along the medicine's lifecycle	6
2.3. Types of patient experience data	8
2.3.1. Patient-reported outcomes	8
2.3.2. Patient preference studies	9
2.3.3. Data obtained through patient engagement activities	11
2.4. Sources of patient experience data	13
2.4.1. Patient experience data collected in clinical trials	14
2.4.2. Real-world data as a source of patient experience data	14
2.4.3. Safety surveillance systems	15
2.4.4. Other potential sources of patient experience data	15
2.5. Considerations for systematic implementation of patient experience data	15
2.5.1. Data quality	15
2.5.2. Representativeness	16
2.5.3. Study design	16
2.5.4. Data collection methods and tools	16
2.5.5. Challenges related to the use of PROs	17
2.5.6. Participant burden	17
2.5.7. Training and capacity building	17
2.5.8. Language	17
2.5.9. Perceived lack of value	18
2.5.10. Transparency on the use of PED in regulatory assessment	18
2.5.11. Global alignment on patient experience data	18
3. Conclusions	19
4. References	
5. Glossary	

Call to Action!

Express your views on the Reflection
Paper on Patient Experience Data
Consultation until 31 January 2026

